

510(K) Summary of Safety and Efficacy

Gendron Regency Power Wheelchair

16001923

AUG 25 2000

A. General Information

1. **Submitter:** Gendron, Inc.
400 E. Lugbill Road
Archbold, Ohio 43502
2. **Telephone:** 419-445-6060
3. **Facsimile:** 419-446-2631
4. **Contact Person:** Frederic W Strobel
5. **e-mail:** fstrobel@gendroninc.com
6. **Date Prepared:** 30 May 2000
7. **Registration Number:** 1523528

B. Device

1. **Name of the Device:** Regency Power Wheelchair (7200, 7500, & 7800)
2. **Trade Name:** Regency Power Wheelchair
3. **Common Name:** Power Wheelchair
4. **Classification Name:** Power Wheelchair
5. **Product Code:** 89 (Physical Medicine Devices Panel)
6. **Class:** II
7. **Registration Number:** 890. 3860

C. Identification of Legally Marketed devices

- 1.1 **Name:** Permobil Power Wheelchair (1280)
- 1.2 **K Number:** (K991658)
- 1.3 **Date Cleared:** 8 October 1999
- 2.1 **Name:** Wheelchairs of Kansas Power Wheelchair
- 2.2 **K Number:** (K970743)
- 3.3 **Date Cleared:** 30 April 1997



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D. Intended Use

The Gendron Regency powered wheelchair provides a means of mobility for a person who is restricted to a sitting position. This includes all age groups with varying medical and physical conditions.

E. Description of device

Regency Power Wheelchair is a battery powered, rear wheel motor driven and controlled by the Penny & Giles power wheelchair Pilot + controller. The Joystick is user interfaced. It transfers the commands of the user to drive the chair.

The wheelchair is powered by two 22 NF batteries. With a user load of 880 pounds and a fully charged battery, the theoretical driving range is 3.5 miles.

The chair frame is of welded steel construction and includes two rear drive wheels with drive units (motor, gear & brake), batteries and front pivoting casters. Depending on user needs, the joystick motor control is mounted to the left or right armrest.

When the user activates the joystick, the controller receives a signal to release the brakes. With the brakes released, the chair is allowed to move in the direction the joystick is actuated. When the user releases the joystick, the chair slows to a stop and the brakes are automatically re-engaged. The solenoid electromechanical brakes allow the user to stop by letting go of the joystick.

Accessories include; electric powered tilt seat, electric power backrest, both manual and electric powered elevating legrest, lap belt, oxygen tank holder, and IV poles.

G. Safety and effectiveness

The Gendron Regency Power Wheelchair has substantially the same technological characteristic as the predicate devices. Any minor design changes declared in this submission do not raise new questions of safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 25 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Frederic W. Strobel
Gendron, Inc.
400 East Lugbill Road
P.O. Box 0197
Archbold, Ohio 43502

Re: K001923

Trade Name: Regency Power Wheelchair Models 7200, 7500 and 7800
Regulatory Class: II
Product Code: ITI
Dated: June 21, 2000
Received: June 23, 2000

Dear Mr. Strobel:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.


This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Page 2 – Mr. Frederic W. Strobel

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Neil R. P. Ogden".

Celia M. Witten, Ph.D., M.D. 

Director

Division of General, Restorative and

Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure



510(K) Indications for Use

Gendron Regency Power Wheelchair

Indications for use: The Gendron Regency powered wheelchair provides a means of mobility to a person who is restricted to a sitting position. This includes all age groups with varying medical and physical conditions.

510(k) Number: K001923

Device Name: Regency Power Wheelchair (7200, 7500, & 7800)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (per 21 CFR 801.109) _____ or Over the Counter X

DMO for cmw

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number: K 001923